

**WE CLAIM:**

1. An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
2. An inhalable powder according to claim 1, wherein the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methyl sulphate thereof.
3. An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
4. An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
5. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 17 to 50  $\mu\text{m}$  and finer excipient with an average particle size of 2 to 8  $\mu\text{m}$ .
6. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the proportion of finer excipient in the total amount of excipient is 3 to 15%.

7. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 0.5 to 10  $\mu\text{m}$ .
8. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein one or more  
5 monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or mixtures thereof are used as the excipients.
9. An inhalable powder according to claim 8, wherein glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium  
10 carbonate or mixtures thereof are used as the excipients.
10. An inhalable powder according to claim 9, wherein glucose or lactose or mixtures thereof are used as the excipients.
- 15 11. A process for preparing an inhalable powder according to one of claims 1 to 4, comprising: (a) mixing coarser excipient fractions with finer excipient fractions to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.
12. A method of treating a disease that is responsive to the administration of tiotropium,  
20 comprising administering to a host in need thereof an inhalable powder according to one of claims 1 to 4.
13. A method according to claim 12, wherein the disease is asthma or COPD.
- 25 14. An inhalette capsule containing an inhalable powder according to one of claims 1 to 4.
15. An inhalette capsule containing from 3 to 10 mg of inhalable powder according to one of claims 1 to 4.
- 30 16. An inhalette capsule according to claim 15, containing between 1.2 and 80  $\mu\text{g}$  of tiotropium.

17. An inhalable powder according to claim 4 comprising 0.1 to 0.8% of tiotropium bromide monohydrate.

5 18. An inhalable powder according to claim 4 comprising 0.2 to 0.5% of tiotropium bromide monohydrate.

19. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 20 to 30  $\mu\text{m}$  and  
10 finer excipient with an average particle size of 3 to 7  $\mu\text{m}$ .

20. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the proportion of finer excipient in the total amount of excipient is 5 to 10%.

15 21. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 1 to 6  $\mu\text{m}$ .

22. An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 2 to 5  $\mu\text{m}$ .

20

23. An inhalable powder according to claim 10, wherein lactose monohydrate is used as the excipient.

25 24. An inhalable powder comprising between 0.2 and 0.5% of tiotropium bromide monohydrate in admixture with lactose monohydrate as the physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 20 to 30  $\mu\text{m}$  and finer excipient with an average particle size of 3 to 7  $\mu\text{m}$ , the proportion of the finer excipient constituting 5 to 10% of the total amount of excipient.

30

25. An inhallette capsule containing from 3 to 10 mg of inhalable powder according to claim 24.
26. An inhallette capsule containing from 4 to 6 mg of inhalable powder according to one  
5 of claims 1 to 4 or 24.
27. An inhallette capsule according to claim 26, containing between 1.6 and 48 µg of tiotropium.
- 10 28. An inhallette capsule according to claim 26, containing between 2 and 60 µg of tiotropium bromide monohydrate.
29. An inhallette capsule according to claim 26, containing between 4 and 48 µg of tiotropium bromide monohydrate.
- 15 30. An inhallette capsule according to claim 26, containing between 8 and 30 µg of tiotropium bromide monohydrate.
31. An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a  
20 physiologically acceptable excipient, said inhalable powder prepared by a process comprising: (a) mixing coarser excipient having an average particle size of 15 to 80 µm and finer excipient having an average particle size of 1 to 9 µm, wherein the proportion of the finer excipient constitutes 1 to 20% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.
- 25 32. An inhalable powder according to claim 31, wherein the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methyl sulphate thereof.
- 30 33. An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, said inhalable powder prepared by

a process comprising: (a) mixing coarser excipient having an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient having an average particle size of 1 to 9  $\mu\text{m}$ , wherein the proportion of the finer excipient constitutes 1 to 20% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the  
5 tiotropium bromide.

34. An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, said inhalable powder prepared by a process comprising: (a) mixing coarser excipient having an average  
10 particle size of 15 to 80  $\mu\text{m}$  and finer excipient having an average particle size of 1 to 9  $\mu\text{m}$ , wherein the proportion of the finer excipient constitutes 1 to 20% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium bromide monohydrate.

15 35. An inhalable powder according to claim 34 comprising 0.1 to 0.8% of tiotropium . bromide monohydrate.

36. An inhalable powder according to claim 34 comprising 0.2 to 0.5% of tiotropium bromide monohydrate.

20

37. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the coarser excipient has an average particle size of 17 to 50  $\mu\text{m}$  and the finer excipient has an average particle size of 2 to 8  $\mu\text{m}$ .

25 38. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the coarser excipient has an average particle size of 20 to 30  $\mu\text{m}$  and the finer excipient has an average particle size of 3 to 7  $\mu\text{m}$ .

30 39. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the proportion of finer excipient in the total amount of excipient is 3 to 15%.

40. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the proportion of finer excipient in the total amount of excipient is 5 to 10%.

41. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the  
5 tiotropium used has an average particle size of 0.5 to 10  $\mu\text{m}$ .

42. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the tiotropium used has an average particle size of 1 to 6  $\mu\text{m}$ .

10 43. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein the tiotropium used has an average particle size of 2 to 5  $\mu\text{m}$ .

44. An inhalable powder according to one of claims 31, 32, 33 or 34, wherein one or more monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or  
15 mixtures thereof are used as the excipients.

45. An inhalable powder according to claim 44, wherein glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium carbonate or mixtures thereof are used as the excipients.

20

46. An inhalable powder according to claim 45, wherein glucose or lactose or mixtures thereof are used as the excipients.

47. An inhalable powder according to claim 46, wherein lactose monohydrate is used as  
25 the excipient.

48. An inhalable powder comprising between 0.2 and 0.5% of tiotropium bromide monohydrate in admixture with lactose monohydrate as a physiologically acceptable excipient, said inhalable powder prepared by a process comprising: (a) mixing coarser  
30 lactose monohydrate excipient having an average particle size of 20 to 30  $\mu\text{m}$  and finer lactose monohydrate excipient having an average particle size of 3 to 7  $\mu\text{m}$ , wherein the

proportion of the finer lactose monohydrate excipient constitutes 5 to 10% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium bromide monohydrate.

5     49.     A method of treating a disease that is responsive to the administration of tiotropium, comprising administering to a host in need thereof an inhalable powder according to one of claims 31, 32, 33, 34 or 48.

50.     A method according to claim 49, wherein the disease is asthma or COPD.

10

51.     An inhalette capsule containing an inhalable powder according to one of claims 31, 32, 33, 34 or 48.

52.     An inhalette capsule containing from 3 to 10 mg of inhalable powder according to  
15     one of claims 31, 32, 33, 34 or 48.

53.     An inhalette capsule containing from 4 to 6 mg of inhalable powder according to one of claims 31, 32, 33, 34 or 48.

20     54.     An inhalette capsule according to claim 53, containing between 1.6 and 48 µg of tiotropium.

55.     An inhalette capsule according to claim 53, containing between 2 and 60 µg of tiotropium bromide monohydrate.

25

56.     An inhalette capsule according to claim 53, containing between 4 and 48 µg of tiotropium bromide monohydrate.

57.     An inhalette capsule according to claim 53, containing between 8 and 30 µg of  
30     tiotropium bromide monohydrate.